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RICHARD R. ROOKER, CLERK
D.C.

**IN THE CIRCUIT COURT FOR DAVIDSON COUNTY, TENNESSEE**
**TWENTIETH JUDICIAL DISTRICT AT NASHVILLE**

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| **STATE OF TENNESSEE, *ex rel.* ROBERT E. COOPER, JR., ATTORNEY GENERAL and REPORTER,** | ) | |
| **Plaintiff,** | ) | |
| **v.** | ) | **Case No._____** |
| **PFIZER INC, a Delaware corporation,** | ) | |
| **Defendant.** | ) | |

## AGREED FINAL JUDGMENT

Plaintiff, State of Tennessee, by and through Robert E. Cooper, Jr., the Attorney General and Reporter ("Attorney General", "State of Tennessee" or "State"), pursuant to the Tennessee Consumer Protection Act of 1977, Tenn. Code Ann. § 47-18-101 *et seq.* ("TCPA"), having filed a Complaint at the request of Mary Clement, the Director of the Division of Consumer Affairs of the Department of Commerce and Insurance ("Division"), and Defendant, Pfizer Inc, a foreign corporation, as evidenced by the signatures, consent to the entry of this Agreed Final Judgment ("Judgment") and its provisions. Whenever reference is made in this Agreed Final Judgment to "Pfizer" or "Defendant," these terms mean and include the use set forth in the Definitions below.

Pursuant to Tenn. Code Ann. § 47-18-108, the parties voluntarily enter in this Agreed Final Judgment on the terms and conditions set forth below.

Pfizer expressly waives ten day notice of the Attorney General's intention to file an action pursuant to Tenn. Code Ann. § 47-18-108(a)(2). Pfizer hereby accepts and expressly waives any defects in connection with service of process issued on Pfizer by the State and if no

service has issued, Pfizer expressly agrees and waives the requirement that the State issue service of process of the Complaint.

Pfizer expressly waives and relinquishes any defense, requirement, or argument that the permanent injunction below does not contain a finding of fact or conclusion of law.

**NOW THEREFORE**, upon the consent of the parties hereto, **IT IS HEREBY ORDERED, ADJUDGED AND DECREED AS FOLLOWS**:

**1.**

**DEFINITIONS:**

a. "**Covered Conduct**" shall mean Pfizer's promotional and marketing practices regarding the prescription drugs Celebrex® and Bextra® that were the subject of an investigation by the Signatory Attorneys General under the State Consumer Protection Laws.

b. "**Effective Date**" shall mean the date by which Pfizer and ninety percent (90%) of the States that comprise the Multistate Working Group have executed the Consent Judgment.

c. "**FDA Amendments Act of 2007**" (or "**FDA Amendments Act**" or "**the Act**") shall mean Public Law No. 110-85, which among other things, creates a federal clinical trial registry and results data bank.

d. "**FDA's Guidances for Industry**" shall mean documents published by the United States Department of Health and Human Services, Food and Drug Administration (FDA), that represent the FDA's current recommendations on a topic.

e. "**Individual States**" and "**State**" shall mean each Signatory Attorney General who is participating in the Multistate Working Group.

f. "**Pfizer**" shall mean Pfizer Inc, and its United States-based affiliates, subsidiaries, predecessors, successors, and assigns.

g. "**Multistate Executive Committee**" shall mean the Attorneys General and their staffs representing Arizona, California, Florida, Illinois, Massachusetts, New York, Ohio, Oregon, Texas, and Vermont.

h. "**Multistate Working Group**" ("MSWG") shall mean the Attorneys General and their staffs representing Alaska, Arizona, Arkansas, California, Connecticut, Florida, District of Columbia, Idaho, Illinois, Iowa, Kansas, Kentucky, Maine, Maryland, Massachusetts, Michigan, Montana, Nebraska, Nevada, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oregon, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Vermont, Washington, and Wisconsin.

i. "**Off-Label**" shall mean related to an indication that was not approved by the FDA at the time of dissemination or relating to information that was not contained in the FDA label.

j. "**Prescriber**" shall mean any physician, dentist, physician assistant, nurse practitioners, and all others with legal authority to prescribe any Pfizer product, as well as pharmacists, members of Pharmacy & Therapeutics committees and others who potentially have an impact on the prescribing of any Pfizer product.

k. "**Parties**" shall mean Pfizer and the Individual States.

l. "**Product**" shall mean any prescription drug or biological product manufactured, distributed, sold, marketed or promoted in the United States in any way.

m. "**Signatory Attorney(s) General**" shall mean the Attorney General, or his or her designee, of each state in the Multistate Working Group.

n. "**State Consumer Protection Laws**" shall mean the consumer protection laws under which the Signatory Attorneys General have conducted their investigation.[1]

o. "**Celebrex**" shall mean celecoxib.

p. "**Bextra**" shall mean valdecoxib.

**2.**

Pursuant to Tenn. Code Ann. § 47-18-108, the parties have agreed to resolve the issues raised by the Covered Conduct by entering into this Agreed Final Judgment (hereinafter "Judgment").

(a) Pfizer is entering into this Judgment solely for the purpose of settlement, and nothing contained herein may be taken as or construed to be an admission or concession of any

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[1] The States' consumer protection statutes are: ALASKA - *Unfair Trade Practices and Consumer Protection Act*, AS 45.50.471 *et seq.*; ARIZONA - *Consumer Fraud Act*, A.R.S. § 44-1521 *et seq.*; ARKANSAS - Ark. Code Ann. § 4-88-101 *et seq.*; CALIFORNIA - Bus. & Prof. Code §§ 17200 *et seq.* and 17500 *et seq.*; CONNECTICUT - Conn. Gen. Stat. §§ 42-110a *et seq.*; DISTRICT OF COLUMBIA - *Consumer Protection Procedures Act*, D.C. Code § 28-3901 *et seq.*; FLORIDA - *Deceptive and Unfair Trade Practices Act*, Fla. Stat. Ch. 501.201 *et seq.*; IDAHO - *Consumer Protection Act*, Idaho Code Section § 48-601 *et seq.*; ILLINOIS - *Consumer Fraud and Deceptive Business Practices Act*, 815 ILCS § 505/1 *et seq.* (2006 State Bar Edition); IOWA - *Iowa Consumer Fraud Act*, Iowa Code Section 714.16; KANSAS - *Consumer Protection Act*, K.S.A. 50-623 *et seq.*; KENTUCKY - *Consumer Protection Statute*, KRS 367.110 *et seq.*; MAINE - *Unfair Trade Practices Act*, 5 M.R.S.A. § 207 *et seq.*; MARYLAND - *Consumer Protection Act*, Md. Code Ann., Com. Law § 13-101 *et seq.*; MASSACHUSETTS - *Consumer Protection Act*, M.G.L. c. 93A *et seq.*; MICHIGAN - *Michigan Consumer Protection Act*, MCL 445.901 *et seq.*; MONTANA - Mont. Code Ann. § 30-14-101 *et seq.*; NEBRASKA - *Uniform Deceptive Trade Practices Act*, NRS § 87-301 *et seq.*; NEW JERSEY - *New Jersey Consumer Fraud Act*, 56:8-1 *et seq.*; NEW YORK - General Business Law Article 22-A Sections 349, 350 and Executive Law Section 63 (12); NEW MEXICO - *Unfair Practices Act*, NMSA 1978, § 57-12-1 *et seq.*; NEVADA - *Deceptive Trade Practices Act*, Nevada Revised Statutes 598.0903 *et seq.*; NORTH CAROLINA - *Unfair and Deceptive Trade Practices Act*, N.C. Gen. Stat. § 75-1.1 *et seq.*; NORTH DAKOTA - *Unlawful Sales or Advertising Practices*, N.D. Cent. Code. § 51-15-02 *et seq.*; OHIO - *Consumer Sales Practices Act*, R.C. 1345.01 *et seq.*; OREGON - *Unlawful Trade Practices Act*, ORS 646.605 to 646.656; PENNSYLVANIA - *Unfair Trade Practices and Consumer Protection Law*, 73 P.S. § 201-1 *et seq.*; SOUTH CAROLINA - *Unfair Trade Practices Act*, S.C. CODE. ANN. Sections 39-5-10 *et seq.*; SOUTH DAKOTA - *Deceptive Trade Practices Act*, S.D. Codified Laws § 37-24 *et seq.*; TENNESSEE - *Consumer Protection Act*, Tenn. Code Ann. §§ 47-18-101 *et seq.*; TEXAS - *Deceptive Trade Practices - Consumer Protection Act*, Tex. Bus. and Com. Code § 17.47 *et seq.*; VERMONT - *Consumer Fraud Act*, 9 V.S.A. § 2451 *et seq.*; WASHINGTON - *Unfair Business Practices/Consumer Protection Act*, R.C.W. 19.86 *et seq.*; WISCONSIN - Wis. Stat. § 100.18 *et seq.* (Fraudulent Representations) and Wis. Stat. § 100.182 *et seq.* (Fraudulent Drug Advertising).

violation of law, rule, or regulation, or of any other matter of fact or law, or of any liability or wrongdoing, all of which Pfizer expressly denies. Pfizer does not admit any violation of the State Consumer Protection Laws set forth in footnote 1, and does not admit any wrongdoing that was or could have been alleged by any Attorney General before the date of the Judgment under those laws. No part of this Judgment, including its statements and commitments, shall constitute evidence of any liability, fault, or wrongdoing by Pfizer. This document and its contents are not intended for use by any third party for any purpose, including submission to any court for any purpose.

(b) This Judgment shall not be construed or used as a waiver or limitation of any defense otherwise available to Pfizer in any action, or of Pfizer's right to defend itself from, or make any arguments in, any private individual, regulatory, governmental, or class claims or suits relating to the subject matter or terms of this Judgment. This Judgment is made without trial or adjudication of any issue of fact or law or finding of liability of any kind. Notwithstanding the foregoing, a State may file an action to enforce the terms of this Judgment.

(c) It is the intent of the Parties that this Judgment not be admissible in other cases or binding on Pfizer in any respect other than in connection with the enforcement of this Judgment.

(d) No part of this Judgment shall create a private cause of action or confer any right to any third party for violation of any federal or state statute except that a State may file an action to enforce the terms of this Judgment.

(e) All obligations undertaken by Pfizer in this Judgment shall apply prospectively, except to the extent permitted by the National Library of Medicine, Pfizer shall submit, as soon as practicable, clinical trial results to the clinical trial registry and results data bank created by

the FDA Amendments Act for all "applicable clinical trials" (as that term is defined by the Act) of FDA-approved Pfizer Products that were initiated after July 1, 2005.

Accordingly, pursuant to the Tennessee Consumer Protection Act of 1977, Tenn. Code Ann. § 47-18-101, et seq. and Tenn. Code Ann. § 47-18-108(b)(2), Pfizer is hereby enjoined, required and bound as set forth in the following paragraphs and sections:

**3.**

Pfizer shall register clinical trials and submit results to the registry and results data bank as required by the FDA Amendments Act and any accompanying regulations that may be promulgated pursuant to that Act.

**4.**

Pfizer shall not make any written or oral claim that is false, misleading or deceptive regarding any FDA-approved Pfizer Product.

**5.**

Pfizer shall not make any written or oral promotional claims of safety or effectiveness for any FDA-approved Pfizer Product in a manner that violates the Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.* ("FDCA"), accompanying regulations, or voluntary agreements with FDA, as interpreted by the FDA in a writing by the Director of the Center for Drug Evaluation at the FDA.

**6.**

Nothing in this Judgment shall require Pfizer to:

(a) Take an action that is prohibited by the FDCA or any regulation promulgated thereunder, or by FDA; or

(b) fail to take an action that is required by the FDCA or any regulation promulgated thereunder, or by FDA. Any written or oral promotional claim subject to this Judgment which is

the same, or materially the same, as the language required or agreed to by the Director of Division of Drug Marketing, Advertising and Communication or the Director of the Center for Drug Evaluation and Research or their authorized designees in writing shall not constitute a violation of this Judgment.

**7.**

Following the initial approval of any Pfizer Product indicated for pain relief, Pfizer shall delay direct to consumer ("DTC") television advertising that relates to such indication, if the Director of the Center for Drug Evaluation and Research at FDA recommends such a delay in writing to Pfizer. Pfizer's delay shall be for the same period as recommended by the Director of the Center for Drug Evaluation and Research at FDA, but in no event shall the period of delay required by this provision of this Judgment exceed 18 months from approval. Should Pfizer run television DTC advertising contrary to a recommendation from the Director of the Center for Drug Evaluation and Research after the expiration of this 18 month period, Pfizer shall provide written notice to the Multistate Executive Committee 30 days prior to running the subject advertisement and shall also provide a copy of all correspondence with FDA relating to the subject advertisement.

**8.**

Pfizer agrees to submit all new DTC television advertising campaigns for any Pfizer Product to FDA for pre-review; to wait a reasonable time (not less than 45 days) until Pfizer receives a response from FDA prior to running the advertising campaign, and to modify such advertising consistent with any written comments from FDA, whenever received. Simultaneous with running any new DTC television advertisement for which FDA has not provided Pfizer with a pre-review response addressing the substance of the advertisement within the 45-day waiting period prescribed herein, Pfizer shall provide written notice to the Multistate Executive

Committee that Pfizer is running the advertisement and that the FDA has not provided Pfizer with a pre-review response addressing the substance of the advertising within the 45-day waiting period, and also provide a copy of all material submitted to FDA for the review of the subject advertisement.

**9.**

Pfizer's obligations with respect to Paragraph 7 shall remain in effect for eight (8) years following the Effective Date. Pfizer's obligations with respect to Paragraph 8 shall remain in effect for seven (7) years following the Effective Date. With respect to Paragraph 7, Pfizer shall abide by any such written recommendation so long as the submission of the TV advertising campaign is made within eight years following the Effective Date. With respect to Paragraph 8, Pfizer shall abide by any such written recommendation so long as the submission of the TV advertising campaign is made within seven (7) years of the Effective Date.

**10.**

When presenting information in detailing pieces, brochures, booklets, mailing pieces, published journals, magazines, other periodicals and newspapers, and broadcast through media such as radio, television, the Internet, and telephone communications systems, about a Clinical Study that relates to an FDA-approved Pfizer Product, Pfizer shall: (a) accurately reflect the methodology used to conduct the Clinical Study; (b) not present favorable information or conclusions from a study that is inadequate in design, scope, or conduct to furnish significant support for such information or conclusions; and (c) not use statistical analyses and techniques on a retrospective basis to discover and cite findings not soundly supported by the study, or to suggest scientific validity and rigor for data from studies the design or protocol of which are not amenable to formal statistical evaluations.

**11.**

When presenting information in detailing pieces, brochures, booklets, mailing pieces, published journals, magazines, other periodicals and newspapers, and broadcast through media such as radio, television, the Internet, and telephone communications systems, about a Clinical Study or analysis of Clinical Studies as evidence of an FDA-approved Pfizer Product's safety, Pfizer shall not: (a) present information from a study in a way that implies that the study represents larger or more general experience with the drug than it actually does; or (b) use statistics on numbers of patients, or counts of favorable results or side effects derived from pooling data from various insignificant or dissimilar studies in a way that suggests either that such statistics are valid if they are not or that they are derived from large or significant studies supporting favorable conclusions when such is not the case.

**12.**

When presenting information in detailing pieces, brochures, booklets, mailing pieces, published journals, magazines, other periodicals and newspapers, and broadcast through media such as radio, television, the Internet, and telephone communications systems, about a Clinical Study or analysis of Clinical Studies as evidence of an FDA-approved Pfizer Product's safety, Pfizer shall not: (a) present favorable information or conclusions from a study that is inadequate in design, scope, or conduct to furnish significant support for such information or conclusions; (b) use the concept of statistical significance to support a claim that has not been demonstrated to have clinical significance or validity, or fails to reveal the range of variations around the quoted average results; or (c) use statistical analyses and techniques on a retrospective basis to discover and cite findings not soundly supported by the study, or to suggest scientific validity and rigor for data from studies the design or protocol of which are not amenable to formal statistical evaluation.

**13.**

(a) Pfizer shall comply with the ACCME Standards for Commercial Support (a copy of the current version is attached hereto as Appendix 1).

(b) Any person who acts in a promotional capacity for Pfizer with respect to an FDA approved Pfizer Product shall be obligated under his or her contract with Pfizer, as a condition for any future promotional relationship with Pfizer, to disclose to Continuing Medical Education ("CME") participants orally and to the CME provider for inclusion in the written materials the existence, nature and purpose of his or her arrangement with Pfizer when a member of the faculty at a CME program if: (i) the Product the faculty member promoted for Pfizer is in the same therapeutic category as the subject of the CME program, and (ii) the CME program occurs within 12 months of the faculty member performing work for or receiving compensation from Pfizer. Such disclosure shall set forth the type of promotional work engaged in by the faculty member and the name of the therapeutic category with respect to which such promotion was performed.

(c) Pfizer shall not provide funding for CME when Pfizer has knowledge at the time the decision to fund the CME is made that a speaker at the CME has also been a promotional speaker in the past twelve (12) months at a Pfizer-sponsored promotional event related to the class of drugs to be discussed in the CME.

**14.**

Pfizer's obligations with respect to CME shall remain in effect for nine (9) years following the Effective Date. Pfizer's obligations with respect to Paragraph 13(b) shall only apply to speakers' contracts entered into, amended to extend the contract period, or renewed after the date of this Judgment.

**15.**

Pfizer shall require all individuals who are named as authors on a Pfizer-sponsored manuscript reporting the results of a Pfizer-sponsored study to fulfill the following conditions: (a) the individual shall have made a substantial contribution to the conception and design, or acquisition of data, or analysis and interpretation of data; (b) the individual shall have been involved in drafting the article or revising it critically for important intellectual content; and (c) the individual shall have final approval rights of the version to be published.

**16.**

When a large, multi-center group has conducted the research, the manuscript shall identify the individuals who accept direct responsibility for the manuscript. These individuals should fully meet the criteria for authorship defined in Paragraph 15 above.

**17.**

Pfizer shall not disseminate in a promotional context any patient testimonial relating to a Product that does not clearly and conspicuously disclose what the generally expected performance would be in the depicted circumstances or clearly and conspicuously disclose the limited applicability of the experience described by the patient testimonial to what consumers may generally expect to achieve.

**18.**

Pfizer shall not market two or more Products in a manner that falsely or misleadingly conflates the various properties of the respective Products.

**19.**

Pfizer shall not compensate physicians for conducting individual, observational teaching sessions in their offices or in the hospital ("mentorships") in which sales representatives who detail a Product participate.

**20.**

Pfizer shall instruct investigators of Pfizer sponsored clinical trials regarding a Product to obtain a legally effective informed consent from all study subjects or from the subject's legally authorized representative. If Pfizer provides the investigator (or the investigator's Institutional Review Board) with a model informed consent, Pfizer shall not fail to include: (a) a statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental; (b) a description of any reasonably foreseeable risks or discomforts to the subject; and (c) for research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.

**21.**

Pfizer shall not affirmatively seek the inclusion of a Product in hospital protocols or standing orders unless the Product at issue has been approved by the FDA for the indication for which it is to be included in the protocol or standing order. Notwithstanding the foregoing, Pfizer may disclose to insurance companies and other third party payors any information regarding the inclusion of a Product in hospital protocols or standing orders even if the Product at issue has not been approved by the FDA for the indication for which it is to be included in the protocol or standing order.

**22.**

Pfizer shall not award prizes or other incentives to its sales force as rewards for specifically increasing the Off-Label use of a Product.

**23.**

Pfizer shall not disseminate any information describing any Off-Label use of a Product if such use has been submitted to the FDA for approval and the FDA has either advised Pfizer that it refuses to approve such application or that the FDA-identified deficiencies must be resolved before approval can be granted unless Pfizer has first clearly and conspicuously disclosed to the information recipient that FDA had issued such advice regarding such Off-Label use. Pfizer may disclose to any recipient of such information whether the information was presented to the FDA prior to the FDA's issuance of such advice regarding the Off-Label use.

**24.**

Pfizer shall not disseminate a Medical Information Letter, an unabridged reprint or copy of an article from a Peer Reviewed Journal or a Reference Publication, or written information through a Regional Medical Research Specialist ("RMRS") describing any Off-Label use of a Product in response to an unsolicited request by a prescriber or other health care professional unless: (a) the information is about a clinical investigation with respect to the Product and experts qualified by scientific training or experience to evaluate the safety or effectiveness of the Product would consider the subject of the clinical investigation to be scientifically sound or the information is an unabridged reprint or copy of an article from a Peer Reviewed Journal or a Reference Publication; (b) the information is accompanied by a comprehensive bibliography of publications discussing adequate and well-controlled clinical studies published in a medical journal or medical or scientific text that have been previously published about the use of the Product covered by the information (unless the information is a Peer Reviewed Journal or Reference Publication which already includes such a bibliography); and (c) in cases in which experts qualified by scientific training or experience to evaluate the safety or effectiveness of the Product would consider the conclusion of the information to have been specifically called into

question by another article(s) or text(s) that experts qualified by scientific training or experience to evaluate the safety or effectiveness of the Product would consider to be scientifically sound, the information must be disseminated with a representative publication that reaches contrary or different conclusions regarding the Off-Label use.

**25.**

Pfizer shall not disseminate any reprint or copy of an article from a Peer Reviewed Journal or a Reference Publication describing any Off-Label use of the Product to physician specialties that do not customarily prescribe the Product if these materials combined with detailing, advertising, sampling, or other promotional activities promote Off-Label use of the Product.

**26.**

In the event that the FDA issues a final "Guidance For Industry: Good Reprint Practices For The Distribution Of Medical Journal Articles And Medical Or Scientific Reference Publications On Unapproved New Uses Of Approved Drugs And Approved Or Cleared Medical Devices," and a provision of said Guidance materially conflicts with any of the provisions of Paragraphs 23 through 25 of this Judgment, Pfizer may petition the Court for modification of those paragraphs, after providing thirty (30) days' notice to the Attorney General and Reporter. The parties by stipulation may agree to such a modification, which agreement shall be presented to this Court for consideration provided that the parties may jointly agree to a modification only by a written instrument signed by or on behalf of both Pfizer and the Attorney General and Reporter. If Pfizer wishes to seek a stipulation for a modification from the State, it shall send a written request for agreement to such modification to the Attorney General at least 30 days prior to filing a motion with the Court for such modification. Within 30 days of receipt from Pfizer of a written request for agreement to modify, the Attorney General and Reporter shall notify Pfizer

in writing if the Attorney General and Reporter agree to the requested modification. The Attorney General and Reporter shall not unreasonably withhold his/her consent to the modification. The parties agree it would be unreasonable to withhold consent to the terms provided in the draft "Guidance For Industry: Good Reprint Practices For The Distribution Of Medical Journal Articles And Medical Or Scientific Reference Publications On Unapproved New Uses Of Approved Drugs And Approved Or Cleared Medical Devices," dated February 15, 2008, and attached hereto as Appendix 2, in the event that all such terms are included in the final Guidance For Industry. In the event that all such terms are not included in the final Guidance for Industry, the parties agree to consider whether any such terms that are included in the final Guidance for Industry should form the basis of a modification of Paragraphs 23 through 25 of this Judgment.

**27.**

Pfizer shall not disseminate any Medical Information Letter describing any Off-Label use of a Product that makes any false or misleading representation regarding a Product.

**28.**

Pfizer shall not disseminate samples of a Product with the intent of increasing Off-label prescribing of the Product.

**29.**

When submitting clinical trials relating to Off-label indications to journals for publication, Pfizer shall disclose to the journal that the FDA has not approved the drug for the indication that was the subject of the clinical trial.

**30.**

The Pfizer Medical Education Grants Office shall manage all requests for funding related to CME regarding Products. Approval decisions shall be made by the Pfizer Medical Education

Grants Office alone, and shall be kept separate from the Sales and Marketing function. Notwithstanding the foregoing, decisions to approve a request for funding made by the Pfizer Medical Education Grants Office may be subject to actual funding approval by Pfizer's Chief Financial Officer or other designated officials.

**31.**

Pfizer shall not use grants to advantage or promote Products. This provision includes, but is not limited to, the following prohibitions:

(a) Sales and Marketing personnel shall not initiate, coordinate or implement grant applications on behalf of any customer or Prescriber;

(b) Sales and Marketing personnel shall not be involved in selecting grantees or CME-funded speakers; and

(c) Sales and Marketing personnel shall not measure or attempt to track in any way the impact of grants or speaking fees on the participating Prescribers' subsequent prescribing habits, practices or patterns.

**32.**

Pfizer Sales and Marketing personnel shall not approve grant requests regarding Products, nor attempt to influence the Pfizer Medical Education Grants Office to reward any customers or Prescribers with grants for their prescribing habits, practices or patterns.

**33.**

By its execution of this Judgment, State of Tennessee releases Pfizer and all of its past and present subsidiaries, affiliates, predecessors and successors (collectively, the "Released Parties") from the following: all civil claims, causes of action, damages, restitution, fines, costs, and penalties on behalf of the State of Tennessee under the Tennessee Consumer Protection Act

of 1977, Tenn. Code Ann. § 47-18-101 *et seq.* arising from the Covered Conduct that is the subject of this Judgment.

**34.**

Notwithstanding any term of this Judgment, specifically reserved and excluded from the Release in Paragraph 33 as to any entity or person, including Released Parties, are any and all of the following:

(a) Any criminal liability that any person or entity, including Released Parties, has or may have to the State of Tennessee.

(b) Any civil or administrative liability that any person or entity, including Released Parties, has or may have to the State of Tennessee not expressly covered by the release in Paragraph 33 above, including but not limited to any and all of the following claims:

i) State or federal antitrust violations;

ii) Reporting practices, including "best price," "average wholesale price" or "wholesale acquisition cost;"

iii) Medicaid violations, including federal Medicaid drug rebate statute violations, Medicaid fraud or abuse, and/or kickback violations related to any State's Medicaid program; and,

iv) State false claims violations.

(c) Any liability under the State of Tennessee's above-cited consumer protection laws which any person or entity, including Released Parties, has or may have to individual consumers or State program payors of said State, and which have not been specifically enumerated as included herein.

(d) As set forth in Paragraph 38, the State's right to enforce the terms of this Judgment against the Defendants for future violations of this Judgment or state law.

**35.**

Within ten (10) days of the Effective Date of this Judgment, Pfizer shall pay a total amount of **SIXTY MILLION DOLLARS** ($60,000,000.00) to be divided and paid by Pfizer directly to each Signatory Attorney General in an amount to be designated by and in the sole discretion of the Multistate Executive Committee. The State of Tennessee shall receive **NINE HUNDRED NINETY THOUSAND NINE HUNDRED ELEVEN DOLLARS** ($990,911.00) of this payment. The funds received by the State of Tennessee, shall be distributed and paid as follows:

a. Pursuant to Tenn. Code Ann. § 47-18-108(a)(5) and Tenn. Code Ann. § 47-18-108 (b)(4), **TWO HUNDRED THOUSAND NINE HUNDRED ELEVEN DOLLARS** ($200,911.00) shall be paid to the State of Tennessee, Attorney General for attorneys' fees and costs of investigation, prosecution and monitoring for compliance of this matter, which may be used for consumer protection or other lawful purposes at discretion of the Attorney General.

b. **FIFTY-FIVE THOUSAND DOLLARS** ($ 55,000.00) shall be paid to the State of Tennessee, Division of Consumer Affairs to fund consumer education project(s) selected at the sole discretion of the Director of the Division of Consumer Affairs or to fund investigations and/or litigation pursuant to the Tennessee Consumer Protection Act of 1977 selected at the sole discretion of the Director of the Division of Consumer Affairs.

c. Pursuant to Tenn. Code Ann. § 47-18-108(b)(3), **SEVEN HUNDRED THIRTY-FIVE THOUSAND DOLLARS** ($735,000.00) shall be paid to the State of Tennessee General Fund.

d. Any other or additional sums received by the State of Tennessee shall be paid to the State of Tennessee, Attorney General which may be used for consumer protection purposes or other lawful purposes at the sole discretion of the Attorney General.

e. If the entire amount anticipated by the State of Tennessee is not received or is received over time, any monies received shall first be attributed to attorneys' fees pursuant to paragraph 35 a, next to 35c. and finally to paragraph 35b.

**36.**

For the purposes of resolving disputes with respect to compliance with this Judgment, should any of the Signatory Attorneys General have a reasonable basis to believe that Pfizer has engaged in a practice that violates a provision of this Judgment subsequent to the Effective Date of this Judgment, then such Attorney General shall notify Pfizer in writing of the specific objection, identify with particularity the provisions of this Judgment that the practice appears to violate, and give Pfizer thirty (30) days to respond to the notification; provided, however, that a Signatory Attorney General may take any action if the Signatory Attorney General concludes that, because of the specific practice, a threat to the health or safety of the public requires immediate action.

Upon receipt of written notice, Pfizer shall provide a good-faith written response to the Attorney General notification, containing either a statement explaining why Pfizer believes it is in compliance with the Judgment, or a detailed explanation of how the alleged violation occurred and a statement explaining how Pfizer intends to cure the alleged breach. Nothing in this paragraph shall be interpreted to limit the state's Civil Investigative Demand ("CID"), Request for Consumer Protection Information ("Request") or subpoena authority, to the extent such authority exists under applicable state law, and Pfizer reserves all of its rights with respect to a CID, Request or subpoena issued pursuant to such authority.

**37.**

Upon giving Pfizer thirty (30) days to respond to the notification described above, the Signatory Attorney General shall also be permitted reasonable access to inspect and copy

relevant, non-privileged, non-work product records and documents in the possession, custody or control of Pfizer that relate to Pfizer's compliance with each provision of this Judgment. If the Signatory Attorney General makes or requests copies of any documents during the course of that inspection, the Signatory Attorney General will provide a list of those documents to Pfizer.

**38.**

The State may assert any claim that Pfizer has violated this Judgment in an action to enforce this Judgment, or to seek any other relief afforded by law, but only after providing Pfizer an opportunity to respond to the notification described in Paragraph 36 above; provided, however, that a Signatory Attorney General may take any action if the Signatory Attorney General concludes that, because of the specific practice, a threat to the health or safety of the public requires immediate action.

**39.**

This Judgment represents the full and complete terms of the settlement entered into by the parties hereto. In any action undertaken by either the Attorneys General, or any of them, or Pfizer, no prior versions of this Judgment, and no prior versions of any of its terms, that were not entered by the Court in this Judgment, may be introduced for any purpose whatsoever.

**40.**

a. Jurisdiction of this Court over the subject matter and over the Defendant for the purpose of entering into and enforcing this Judgment is admitted. Jurisdiction is retained by this Court for the purpose of enabling the State to apply to this Court for such further orders and directions as may be necessary or appropriate for the construction, modification or execution of this Judgment, including the enforcement of compliance with this Judgment and penalties for violation thereof.

b. Pursuant to Tenn. Code Ann. § 47-18-107, venue as to all matters between the parties relating hereto shall be in Davidson County, Tennessee.

c. Nothing in this Judgment shall be construed to waive any claims of Sovereign Immunity the State may have in any action or proceeding.

d. This Judgment may only be enforced by the parties hereto.

e. Defendant has, by signature of its counsel hereto, waived any right to appeal, petition for certiorari, move to reargue or rehear or be heard in connection with any judicial proceedings upon this Judgment.

f. Nothing in this Judgment shall be construed to affect any private right of action that a consumer may hold against Defendant.

g. Nothing in this Judgment shall be construed as relieving the Defendant of the obligation to comply with all state and federal laws, regulations or rules, nor shall any of the provisions of this Judgment be deemed to be permission to engage in any acts or practices prohibited by such law, regulation, or rule.

h. No costs shall be taxed to the State as provided in Tenn. Code Ann. § 47-18-116. Further, no discretionary costs shall be taxed to the State. The costs for filing this Judgment shall be paid out of the money received pursuant to this Judgment.

**IT IS SO ORDERED.**

**DATE OF ENTRY:**

**CIRCUIT COURT JUDGE**
TWENTIETH JUDICIAL DISTRICT

I hereby certify that this is a true copy of original instrument filed in my office this 22nd day of Oct 2008
RICHARD R. BOCKER Clerk
By _____ Deputy Clerk

**AGREED TO BY:**

## DEFENDANT'S SIGNATURE AND ACKNOWLEDGMENT

Defendant and its attorney have read and understand this Agreed Final Judgment and each of its terms. Defendant admits to the jurisdiction of the Court in this matter and consents to the entry of this Judgment. Defendant agrees to each and every term contained herein. I, MARKUS GREEN being first duly sworn on oath, depose and say that I am an officer of Pfizer Inc and am fully authorized and empowered to sign this Agreed Final Judgment on behalf of Pfizer Inc as defined above and bind the same to the terms hereof.

Markus Green
Corporate Counsel
Pfizer Inc

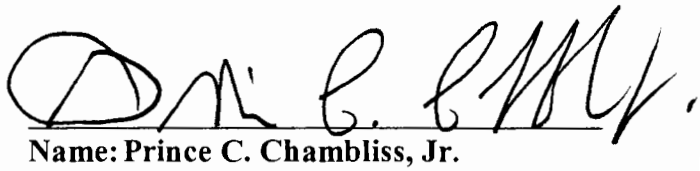
SUBSCRIBED AND SWORN to before

me this 14th day of October, 2008.

Peggy A. Smallwood
Notary Public
My Commission Expires: January 14, 2009

PEGGY A. SMALLWOOD
NOTARY PUBLIC DISTRICT OF COLUMBIA
My Commission Expires January 14, 2009

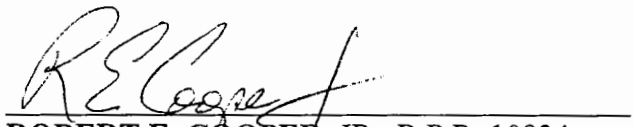
**For the Defendant:**
**Approved as to Form**



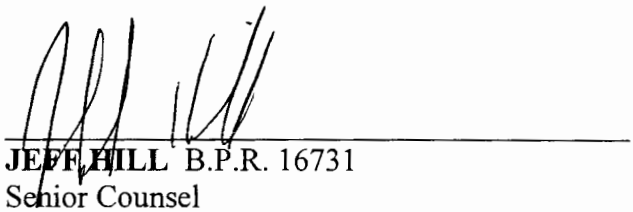
**Name: Prince C. Chambliss, Jr.**
**TN BPR# 005071**
**Address: 1000 Ridgeway Loop Road, Suite 200**
**Memphis, Tennessee 38120**
**Phone: 901-521-4590**
**Fax: 901-374-7486**

Attorney for Pfizer Inc

**STATE OF TENNESSEE ATTORNEY GENERAL AND REPORTER:**



**ROBERT E. COOPER**, JR. B.P.R. 10934
Attorney General and Reporter



**JEFF HILL** B.P.R. 16731
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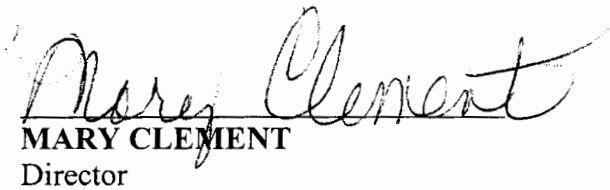
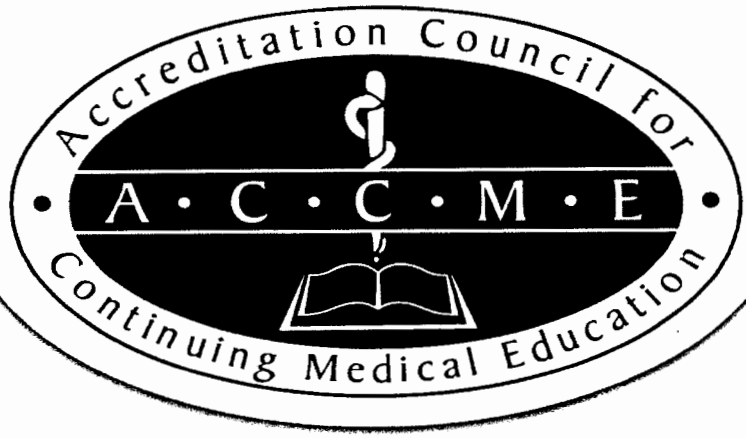


**MARY CLEMENT**
Director
Tennessee Division of Consumer Affairs

# APPENDIX 1




# ACCME STANDARDS FOR COMMERCIAL SUPPORT[SM]

## *Standards* to Ensure the Independence of CME Activities

ACCME

## The ACCME Standards for Commercial Support℠

*Standards* to Ensure Independence in CME Activities

### STANDARD 1: Independence

**1.1** A CME provider must ensure that the following decisions were made free of the control of a commercial interest. (See www.accme.org for a definition of a 'commercial interest' and some exemptions.)

(a) Identification of CME needs;
(b) Determination of educational objectives;
(c) Selection and presentation of content;
(d) Selection of all persons and organizations that will be in a position to control the content of the CME;
(e) Selection of educational methods;
(f) Evaluation of the activity.

**1.2** A commercial interest cannot take the role of non-accredited partner in a joint sponsorship relationship.⌘

### STANDARD 2: Resolution of Personal Conflicts of Interest

**2.1** The provider must be able to show that everyone who is in a position to control the content of an education activity has disclosed all relevant financial relationships with any commercial interest to the provider. The ACCME defines "'relevant' financial relationships" as financial relationships in any amount occurring within the past 12 months that create a conflict of interest.

**2.2** An individual who refuses to disclose relevant financial relationships will be disqualified from being a planning committee member, a teacher, or an author of CME, and cannot have control of, or responsibility for, the development, management, presentation or evaluation of the CME activity.

**2.3** The provider must have implemented a mechanism to identify and resolve all conflicts of interest prior to the education activity being delivered to learners.⌘

### STANDARD 3: Appropriate Use of Commercial Support

**3.1** The provider must make all decisions regarding the disposition and disbursement of commercial support.

**3.2** A provider cannot be required by a commercial interest to accept advice or services concerning teachers, authors, or participants or other education matters, including content, from a commercial interest as conditions of contributing funds or services.

**3.3** All commercial support associated with a CME activity must be given with the full knowledge and approval of the provider.

**Written agreement documenting terms of support**

**3.4** The terms, conditions, and purposes of the commercial support must be documented in a written agreement between the commercial supporter that includes the provider and its educational partner(s). The agreement must include the provider, even if the support is given directly to the provider's educational partner or a joint sponsor.

**3.5** The written agreement must specify the commercial interest that is the source of commercial support.

**3.6** Both the commercial supporter and the provider must sign the written agreement between the commercial supporter and the provider.

**Expenditures for an individual providing CME**

**3.7** The provider must have written policies and procedures governing honoraria and reimbursement of out-of-pocket expenses for planners, teachers and authors.

**3.8** The provider, the joint sponsor, or designated educational partner must pay directly any teacher or author honoraria or reimbursement of out-of–pocket expenses in compliance with the provider's written policies and procedures.

**3.9** No other payment shall be given to the director of the activity, planning committee members, teachers or authors, joint sponsor, or any others involved with the supported activity.

**3.10** If teachers or authors are listed on the agenda as facilitating or conducting a presentation or session, but participate in the remainder of an educational event as a learner, their expenses can be reimbursed and honoraria can be paid for their teacher or author role only.

**Expenditures for learners**

**3.11** Social events or meals at CME activities cannot compete with or take precedence over the educational events.

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**3.12** The provider may not use commercial support to pay for travel, lodging, honoraria, or personal expenses for non-teacher or non-author participants of a CME activity. The provider may use commercial support to pay for travel, lodging, honoraria, or personal expenses for bona fide employees and volunteers of the provider, joint sponsor or educational partner.

**Accountability**

**3.13** The provider must be able to produce accurate documentation detailing the receipt and expenditure of the commercial support. ⌘

## STANDARD 4. Appropriate Management of Associated Commercial Promotion

**4.1** Arrangements for commercial exhibits or advertisements cannot influence planning or interfere with the presentation, nor can they be a condition of the provision of commercial support for CME activities.

**4.2** Product-promotion material or product-specific advertisement of any type is prohibited in or during CME activities. The juxtaposition of editorial and advertising material on the same products or subjects must be avoided. Live (staffed exhibits, presentations) or enduring (printed or electronic advertisements) promotional activities must be kept separate from CME.

- For ***print***, advertisements and promotional materials will not be interleafed within the pages of the CME content. Advertisements and promotional materials may face the first or last pages of printed CME content as long as these materials are not related to the CME content they face **and** are not paid for by the commercial supporters of the CME activity.
- For ***computer based***, advertisements and promotional materials will not be visible on the screen at the same time as the CME content and not interleafed between computer 'windows' or screens of the CME content
- For ***audio and video recording***, advertisements and promotional materials will not be included within the CME. There will be no 'commercial breaks.'
- For ***live, face-to-face CME***, advertisements and promotional materials cannot be displayed or distributed in the educational space immediately before, during, or after a CME activity. Providers cannot allow representatives of Commercial Interests to engage in sales or promotional activities while in the space or place of the CME activity.

**4.3** Educational materials that are part of a CME activity, such as slides, abstracts and handouts, cannot contain any advertising, trade name or a product-group message.

**4.4** Print or electronic information distributed about the non-CME elements of a CME activity that are not directly related to the transfer of education to the learner, such as schedules and content descriptions, may include product-promotion material or product-specific advertisement.

**4.5** A provider cannot use a commercial interest as the agent providing a CME activity to learners, e.g., distribution of self-study CME activities or arranging for electronic access to CME activities. ⌘

## STANDARD 5. Content and Format without Commercial Bias

**5.1** The content or format of a CME activity or its related materials must promote improvements or quality in healthcare and not a specific proprietary business interest of a commercial interest.

**5.2** Presentations must give a balanced view of therapeutic options. Use of generic names will contribute to this impartiality. If the CME educational material or content includes trade names, where available trade names from several companies should be used, not just trade names from a single company. ⌘

## STANDARD 6.Disclosures Relevant to Potential Commercial Bias

**Relevant financial relationships of those with control over CME content**

**6.1** An individual must disclose to learners any relevant financial relationship(s), to include the following information:

- The name of the individual;
- The name of the commercial interest(s);
- The nature of the relationship the person has with each commercial interest.

**6.2** For an individual with no relevant financial relationship(s) the learners must be informed that no relevant financial relationship(s) exist.

**Commercial support for the CME activity.**

**6.3** The source of all support from commercial interests must be disclosed to learners. When commercial support is 'in-kind' the nature of the support must be disclosed to learners.

**6.4** 'Disclosure' must never include the use of a trade name or a product-group message.

**Timing of disclosure**

**6.5** A provider must disclose the above information to learners prior to the beginning of the educational activity. ⌘



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# APPENDIX 2

# Guidance for Industry:

# Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices

**DRAFT GUIDANCE**

**This guidance document is being distributed for comment purposes only**

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit comments to Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For single copies of this draft guidance, please contact: Office of Policy, Food and Drug Administration, 5600 Fishers Lane, rm. 14-101, HF-11, Rockville, MD 20857, (301) 827-3360.

For questions regarding this draft document, contact Jarilyn Dupont, Office of Policy, Food and Drug Administration, (301) 827-3360.

**U.S. Department of Health and Human Services**
**Food and Drug Administration**

**February 2008**

**Contains Nonbinding Recommendations**
*Draft – Not for Implementation*

**Table of Contents**



Contains Nonbinding Recommendations
*Draft – Not for Implementation*

**Guidance for Industry: Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices**

*This draft guidance document represents the Food and Drug Administration's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You may use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, please contact the appropriate FDA staff.*

## I. Introduction

This draft guidance is intended to describe the Food and Drug Administration's (FDA or Agency) current thinking regarding "Good Reprint Practices" with regard to the distribution of medical journal articles and scientific or medical reference publications (referred to generally as medical and scientific information) that discuss unapproved new uses for approved drugs[1] or approved or cleared medical devices marketed in the United States to healthcare professionals and healthcare entities.

FDA's guidance documents, including this draft guidance, do not establish legally enforceable rights or responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word should in Agency guidances means that something is suggested or recommended, but not required.

## II. Background

Section 401 of the Food and Drug Administration Modernization Act (FDAMA (21 U.S.C. § 360aaa, § 551, Federal Food, Drug, and Cosmetic Act (FD&C Act))), described certain conditions under which a drug or medical device manufacturer[2] could choose to disseminate medical and scientific information discussing unapproved uses of approved drugs and cleared or approved medical devices to healthcare professionals and certain entities (including pharmacy benefits managers, health insurance issuers, group health plans, and Federal or State governmental agencies). FDAMA section 401 provided that, if these conditions were met, dissemination of such journal articles or reference publications would not be considered as evidence of the manufacturer's intent that the product be used for an unapproved new use. FDA implementing regulations were codified at 21 C.F.R. Part 99.

In 2000, subsequent to a decision by the United States Court of Appeals for the District of Columbia Circuit, FDA published a Notice (65 Fed. Reg. 14286, March 16, 2000) clarifying the applicability of the FDAMA section 401 provision and the FDA implementing regulations. In that Notice, FDA stated that the statute and implementing regulations constituted a "safe harbor" for a manufacturer that complies with them before and while disseminating journal articles and reference publications about "new uses" of approved or cleared products. If a manufacturer complied with the FDAMA provision, the distribution of such journal articles or reference publications would not be used as evidence of an intent that the product distributed by the manufacturer be used for an unapproved use. The Notice stated that if a manufacturer chose to disseminate materials but not proceed under FDAMA section 401, that failure would not constitute an independent violation of law.

FDAMA section 401 ceased to be effective on September 30, 2006, and the implementing regulations are no longer applicable. In light of the statute's sunset, FDA is providing its current views on the dissemination of medical journal articles and medical or scientific reference publications on unapproved uses of approved drugs and approved or cleared medical devices to healthcare professionals and healthcare entities.

## III. Purpose

As explained in FDA's March 16, 2000 Notice, the FD&C Act and FDA's implementing regulations generally prohibit manufacturers of new drugs or medical devices from distributing products in interstate commerce for any intended use that FDA has not approved as safe and effective or cleared through a substantial equivalence determination. (E.g., FD&C Act §§ 505(a), 502(o), 501(f)(1)(B), 301(a) and (d); 21 U.S.C. §§ 355, 352(o), 351(f)(1)(B), 331(a) and (d)). An approved new drug that is marketed for an unapproved use becomes misbranded and an unapproved new drug with respect to that use. Similarly, a medical device that is promoted for a use that has not been approved or cleared by FDA is adulterated and misbranded.

FDA does, however, recognize the important public policy reasons for allowing manufacturers to disseminate truthful and non-misleading medical journal articles and medical or scientific reference publications on unapproved uses of approved drugs and approved or cleared medical devices to healthcare professionals and healthcare entities. Once a drug or medical device has been approved or cleared by FDA, generally healthcare professionals may lawfully use or prescribe that product for uses or treatment regimens that are not included in the product's approved labeling (or, in the case of a medical device cleared under the 510(k) process, in the product's statement of intended uses). These off-label uses or treatment regimens may be important and may even constitute a medically recognized standard of care. Accordingly, the public health may be advanced by healthcare professionals' receipt of medical journal articles and medical or scientific reference publications on unapproved or new uses of approved or cleared medical products that are truthful and not misleading.

FDA's legal authority to determine whether distribution of medical or scientific information constitutes promotion of an unapproved "new use," or whether such activities cause a product to be misbranded or adulterated has not changed. In recognition of the public health value to healthcare professionals of receiving truthful and non-misleading scientific and medical information, FDA is providing recommendations concerning "Good Reprint Practices" for the dissemination of medical journal articles and medical or scientific reference publications on unapproved uses of drugs and medical devices.[3]

## IV. Agency Recommendations for Good Reprint Practices

Scientific and medical information that concerns the safety or effectiveness of an approved drug or approved or cleared medical device for a new use that is not included in the product's approved labeling or statement of intended uses (including unapproved or new uses of approved drugs and approved or cleared devices) is often published in journal articles or reference publications. These publications are often distributed by manufacturers to healthcare professionals or healthcare entities. When a manufacturer disseminates such medical and scientific information, FDA recommends that the following principles of "Good Reprint Practices" be followed.

### A. Types of Reprints/Articles/Reference Publications

A scientific or medical journal article that is distributed should:

- be published by an organization that has an editorial board that uses experts who have demonstrated expertise in the subject of the article under review by the organization and who are independent of the organization to review and objectively select, reject, or provide comments about proposed articles, and that has a publicly stated policy, to which the organization adheres, of full disclosure of any conflict of interest or biases for all authors, contributors, or editors associated with the journal or organization;
- be peer-reviewed and published in accordance with the peer-review procedures of the organization; and
- not be in the form of a special supplement or publication that has been funded in whole or in part by one or more of the manufacturers of the product that is the subject of the article.

A scientific or medical reference publication that is distributed should not be:

- primarily distributed by a drug or device manufacturer, but should be generally available in bookstores or other independent distribution channels where medical textbooks are sold;
- written, edited, excerpted, or published specifically for, or at the request of, a drug or device manufacturer; or
- edited or significantly influenced by a drug or device manufacturer or any individuals having a financial relationship with the manufacturer.

The information contained in the above scientific or medical journal article or reference publications should address adequate and well-controlled clinical investigations that are considered scientifically sound by experts with scientific training and experience to evaluate the safety or effectiveness of the drug or device[4]. The information must not:

- be false or misleading, such as a journal article or reference text that is inconsistent with the weight of credible evidence derived from adequate and well-controlled clinical investigations (e.g., where a significant number of other studies contradict the article or reference text's conclusions), that has been withdrawn by the journal or disclaimed by the author, or that discusses a clinical investigation where FDA has previously informed the company that the clinical investigation is not adequate and well-controlled; or
- pose a significant risk to the public health.

The following publications are examples of publications that would not be considered consistent with the Good Reprint Practices outlined in this draft guidance:

- letters to the editor;
- abstracts of a publication;
- reports of Phase 1 trials in healthy subjects; or
- reference publications that contain little or no substantive discussion of the relevant investigation or data.

### B. Manner in which to Disseminate Scientific and Medical Information

Scientific or medical information that is distributed should:

- be in the form of an unabridged reprint, copy of an article, or reference publication;
- not be marked, highlighted, summarized, or characterized by the manufacturer in any way;
- be accompanied by the approved labeling for the drug or medical device;
- be accompanied by a comprehensive bibliography of publications discussing adequate and well-controlled clinical studies published in a medical journal or medical or scientific text that have been previously published about the use of the drug or medical device covered by the information disseminated (unless the information already includes such a bibliography);
- in cases where the conclusions of article or text to be disseminated have been specifically called into question by another article(s) or text(s), be disseminated with a representative publication that reaches contrary or different conclusions regarding the unapproved use; and

- be distributed separately from information that is promotional in nature. For example, if a sales representative delivers a reprint to a physician in his office, the reprint should not be physically attached to any promotional material the sales representative uses or delivers during the office visit and should not be the subject of discussion between the sales representative and the physician during the sales visit.[5] Similarly, while reprints may be distributed at medical or scientific conferences in settings appropriate for scientific exchange, reprints should not be distributed in promotional exhibit halls or during promotional speakers' programs.

The journal reprint or reference publication should be accompanied by a prominently displayed and permanently affixed statement disclosing:

- that the uses described in the information have not been approved or cleared by FDA, as applicable to the described drug or medical device;
- the manufacturer's interest in the drug or medical device that is the subject of the journal reprint or reference text;
- any author known to the manufacturer as having a financial interest in the product or manufacturer or receiving compensation from the manufacturer, if applicable;
- any person known to the manufacturer who has provided funding for the study, if applicable; and
- any significant risks or safety concerns known to the manufacturer concerning the unapproved use that are not discussed in the journal article or reference text.

## V. Summary

FDA recognizes that the public health can be served when health care professionals receive truthful and non-misleading scientific and medical information on unapproved uses of approved or cleared medical products. Accordingly, if a manufacturer follows the recommendations described in Section IV of this draft guidance and there is no unlawful promotion of the product, FDA does not intend to use the distribution of such medical and scientific information as evidence of an intent by the manufacturer that the product be used for an unapproved use.[6]

***Footnotes***

[1] As used in this draft guidance, the term "drug" includes biological products licensed under Section 351(a) of the Public Health Service Act. See 42 U.S.C. § 262(j).

[2] As used in this draft guidance, the term "manufacturer" means a person who manufactures a drug or device or who is licensed by such person to distribute or market the drug or device. The term may also include the sponsor of the approved, licensed, or cleared drug or device.

[3] This draft guidance does not apply to scientific or medical information distributed in response to unsolicited requests for scientific or medical information from health care professionals. See 59 Fed. Reg. 59820, 59823 (November 18, 1994).

[4] In the case of medical devices, journal articles or reference publications discussing significant non-clinical research may be consistent with this draft guidance.

[5] To the extent that the recipients of such information have questions, the Agency recommends that the sales representative refer such questions to a medical/scientific officer or department, and that the officer or department to which the referral is made be separate from the sales and/or marketing departments.

[6] Given the sunset of FDAMA § 401, the other elements that comprised § 401 which are not specifically described in this draft guidance are no longer applicable.

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**For More Information**

Press Release *(February 15, 2008)*
*Federal Register* (Docket No. FDA-2008-D-0053, OC 2007268)

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